



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/079,834	05/15/98	MOUNTZ	J D6005

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EXAMINER

TUNG, M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/27/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/079,834

Applicant(s)
Mountz And Zhou

Examiner
Mary Tung

Group Art Unit
1644



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) 10-15 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 16, and 17 is/are rejected.

☒ Claim(s) 8 and 9 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-9, 16 and 17 are drawn to a method of inducing systemic tolerance, classified in class 435, subclass 375.
 - II. Claims 10-12 are drawn to a method of inducing T-cell tolerance in an individual receiving gene therapy, classified in class 424, subclass 93.21.
 - III. Claims 13-15, drawn to a method of increasing expression of a transgene in an individual, classified in class 424, subclass 93.2.
2. Groups I, II and III are unique methods. They differ with respect to ingredients and method steps. A method of inducing immune tolerance using antigen presenting cells, as recited in Group I, a method of inducing T cell tolerance by treating an individual with a virus, as recited in Group II, and a method of increasing expression of a transgene in an individual represent different inventive endeavors and represent patentably distinct subject matter.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and because a search of any or these three distinct inventions would not be co-extensive with a search of the others, an examination and search of two or more inventions in a single application would constitute a serious undue burden on the Examiner, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Dr. Benjamin Aaron Adler on October 9, 1998, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-9. Claims 16 and 17 have been subsequently rejoined by the Examiner as being drawn to the elected invention. Affirmation of this election must be made by applicant in responding to this Office action. Claims 10-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Specification

6. The use of the trademark "GALACTO-LIGHT", page 35, line 9, has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

7. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Abstract

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

9. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. *The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided.* The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

10. The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 2 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. Claim 2 and 7 are substantial duplicates of claim 1. The recited mechanism of the induction of immune tolerance lends no patentable weight to the limitations of the method of claim 1. There appears to be no difference in scope between the two claims, *see MPEP 706.03(k)*.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

15. Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Bellgrau (US Patent #5,759,536).

16. The '536 patent teaches a method of decreasing rejection of a graft in an individual comprising the steps of perfusing donor organ tissue with Fas ligand and introducing said donor organ to the individual (see the abstract and Example 1, in particular). Therefore, the reference teachings anticipate the claimed invention.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under *subsection (f) or (g)* of *section 102* of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 1-7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Süss (Z).
20. Bellgrau, et al. (US Patent No. 5,759,536) teaches a method of inhibiting T-lymphocyte-mediated immune responses by providing a recipient animal with Fas ligand or cells expressing Fas ligand. The '536 patent additionally teaches the use of said method to improve organ transplantation and to treat juvenile diabetes (see the abstract, col. 3, lines 42-55, col. 6, lines 64-68 and claims 1-3 and 7, in particular). However, the '536 patent does not teach the use of antigen presenting cells to express Fas ligand in said method. However, Süss teaches that CD8⁺ dendritic cells express Fas ligand and induces apoptosis of CD4⁺ T cells which results in the down regulation of the immune response. Süss also teaches that the expression of Fas ligand by cell of the anterior chamber of the eye and Sertoli cells provide for the killing of Fas expressing T cells and thus makes these tissues immune-privileged sites. Süss additionally teaches that the same mechanism probably occurs with dendritic cells and that whole animal models are needed to assess the relative importance of different Fas-ligand expressing cells in controlling immune responses (see the abstract, page 1792, col. 2, paragraph 3, page 1793, and page 1795, in particular). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Süss in the method of immunosuppression taught by the '536 patent in order to improve transplantation success or for the treatment of an autoimmune disease such as diabetes, as taught by the '536 patent (see the abstract and col. 3, lines 51-55, in particular). Claim 7 is included because the recited mechanism of cytotoxic T cell decrease is a mechanism which lends no patentable weight to the limitations. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.
21. Claims 1-7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellgrau (US Patent No. 5,759,536) in view of Schuler (Y).
22. Bellgrau has been discussed, supra, in paragraph 20. However, the '536 patent does not teach the use of antigen presenting cells to express Fas ligand in said method. However, Schuler teaches that dendritic cells express Fas ligand and may provide a novel approach to induce tolerance in transplantation and autoimmunity (see the abstract, page 320, col. 2, paragraph 2, and page 321, col. 2, in particular). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use Fas-ligand-expressing dendritic cells, taught by Schuler in the method of immunosuppression taught by the '536 patent in order to induce tolerance for the

treatment of transplantation or autoimmune disease such as diabetes, as taught by Schuler. Claim 7 is included because the recited mechanism of cytotoxic T cell decrease is a mechanism which lends no patentable weight to the limitations. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Allowable Subject Matter

23. Claims 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mountz, et al. (U), teaches the role of apoptosis in autoimmune disease such as systemic lupus erythematosus and rheumatoid arthritis. Mountz, et al., (V) teaches the role of Fas ligand and ICE in apoptosis and autoimmune disease. Suda and Nagata (W) teaches that defects in the Fas-Fas ligand system can lead to autoimmunity and Tewari, et al. (X) teach the role of Crm-A in inhibiting cytotoxic T lymphocyte-mediated apoptosis.
26. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 305-3014 or (703) 308-4242.
26. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mary Tung whose telephone number is (703)308-9344. The Examiner can normally be reached Monday through Friday from 8:30 am to 5:30 pm. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1640 receptionist whose telephone number is (703) 308-0196.

Serial No. 09/079,834

Art Unit 1644

October 26, 1998

Mary B. Tung, Ph.D.

Patent Examiner

Group 1640

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David A. Saunders

DAVID SAUNDERS

PRIMARY EXAMINER

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